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INTRODUCTION:

The study evaluates an intervention designed to facilitate treatment decision making, adjustment, and coping among early-stage prostate cancer patients and their spouse/partners, in a randomized controlled trial. The intervention is based on the Cognitive-Social Health Information Processing (C-SHIP) framework that postulates that decision making is determined by cognitive factors (i.e., perceptions about vulnerability; expectancies and beliefs; values and goals), affective factors (i.e., concerns and worry about the disease and its treatment), as well as self-regulatory skills (i.e., the ability to manage distress and effectively execute recommended behaviors). The goal of the Cognitive and Affective Reactions and Expectations (CARE) Intervention is to facilitate treatment decision making, by improving understanding of disease and treatment related facts, as well as by preparing the patient and his spouse/partner to anticipate the medical and psychological consequences of the disease and its treatment. This is being achieved in the context of a structured counseling session (approximate duration 45 min). Specifically, the patient's and spouse/partner's cognitive and emotional reactions to the following areas are explored: the treatment itself; potential side effects; long-term treatment success; relationship with others; and stress-management strategies. The efficacy of the intervention will be evaluated systematically with General Health Intervention (GHI) serving as a comparison condition, controlling for time and attention. In the GHI condition patients (and their spouse/partners) will receive and discuss current recommendations for general health (i.e., nutrition and stress management) and will explore their own attitudes, beliefs, and feelings on these topics with a health educator. Assessments will be obtained at baseline, and 6 weeks later, to assess treatment decisions, and at 6 months and 12 months post baseline to assess long-term adjustment and coping.

BODY - RESEARCH ACCOMPLISHMENTS:

The following are tasks taken from the approved Statement of Work

Year 3: Task 5

Accrual for our study ended at the end of June 2003. Our total accrual for the study is 459 couples. As of June 2003, our completion rate of CARE and GHI sessions was 74% with 300 sessions (CARE 150;GHI 150) completed out of 408 that were originally scheduled.

(A) Complete Baseline Assessments

Baselines questionnaires have been given to the 300 couples that completed a CARE or GHI session. We have received 244 baseline questionnaires (81%) from patients and 236 baselines (79%) from spouses/partners.

(B) Complete 6-month assessments

As of the end of October 2003, 6 month follow-up questionnaires have been sent to 232 couples with 205 patients (88%) and 160 (69%) spouses/partners returning completed assessments. We estimate that by the end of December 2003, all scheduled 6-month assessments will be mailed out and by February 2004 they should be returned to us.

(C) The 12-month follow-up assessments have been sent to 182 patients and 160 spouse/partners who have been remaining active in the study. Of those sent, we have received questionnaires from 166 patients (91%) and 150 spouse/partners (94%). These participants have completed all of the required assessments (baseline, 6-month and 12-month) for the study.

(D) Questionnaire data have been entered into the centralized database. All questionnaire data, as far as available, have been entered. All data have been checked for accuracy, and frequency information has been computed. Baseline data are complete.

(E) Continue Data Analyses

Over the past year we have continued to explore the data set and to conduct preliminary analyses on the questionnaire data.

a) Data cleaning. We examine all accumulated data for accurateness by performing range and logical checks. In addition, we perform spot checks on 10% of all entered questionnaires to catch data entry mistakes. To date our data has been entered with 99% accuracy.

b) Scale construction. Scale construction is complete. Measures of negative affect, (i.e., POMS), CES-D depression, intrusion and avoidance (i.e., revised impact of event scale; RIES) and quality of life (QOL; FACT-P) have been constructed by combining the appropriate items into scales. The reliability values of these scales are uniformly high: POMS positive affect ($\alpha = .89$); POMS negative affect ($\alpha = .92$); CESD depression ($\alpha = .80$); RIES intrusion ($\alpha = .87$); RIES avoidance ($\alpha = .79$). For the FACT-P and its subscales we have obtained acceptable reliability values: FACT-P physical well being subscale ($\alpha = .75$); FACT-P social well-being subscales ($\alpha = .66$); FACT-P emotional well-being subscale ($\alpha = .73$); functional well-being ($\alpha = .88$); FACT-P prostate-specific additional concerns ($\alpha = .77$). We have not found any differences by intervention/comparison group on any these scales, suggesting that the randomization procedure has been successful.

c) Description of sample. Patients are eligible to participate if they have been diagnosed with localized carcinoma of the prostate, and have not made a treatment decision. As of to date, we have received 244 baseline questionnaires from patients and 236 baselines from spouses/partners (total $N = 480$). Ninety percent of our sample is Caucasian, 9% is African American, and 1% is Hispanic or Asian-American. Half of the sample (52%) has at least a high school education, 25% completed college, and 17% have a post-graduate degree. Approximately half of the patients are retired (51%), 45% are employed, and 4% are either disabled, unemployed, or semi-retired. Patients are on average 64 years old.

d) Evaluation of Intervention sessions. Upon agreeing to participate into the study, couples were randomized into the CARE or the GHI condition. Preliminary analyses of data assessing the acceptability and usefulness of these sessions suggest that both of the sessions are well accepted. For the CARE intervention, 62% of patients indicated that the session was quite a bit or very useful to understand potential side-effects of prostate cancer treatment; 74% indicated that there was enough information to make a treatment

decision; 76.5% thought the information about side-effects was above average, good, or excellent; 74% indicated that the discussion about treatment consequences was above average, good, or excellent; and 64% thought it provided a good or excellent forum to hear the partner's treatment opinions. Most importantly, 71% of patients indicated that the information provided was useful for treatment decision making, that the information was very understandable (95%), and that the focus on patients' values and goals during the session was very important (74%). Overall, 44% rated the sessions as excellent, 35% as good; 6% as above average (the remaining 15% rated the sessions as average or poor (1.6%)).

The GHI session that focused on nutritional needs during prostate cancer treatment was equally well accepted. Patients indicated that the session was quite a bit or very helpful to understand the potential link between nutrition and prostate cancer (52%), and that it quite a bit or very much addressed concerns about nutrition (76%). Patients rated the nutritional information we provided with respect to specific treatment options very highly: for surgery (45% good to excellent); external beam radiation (52% good to excellent). Overall, 26% rated the sessions as excellent, 31% as good; 16% as above average (the remaining 27% rated the sessions as average or poor (9.1%)).

e) Efficacy of intervention. Based on preliminary analyses of the baseline data there were no differences by study group with regard to worry and distress about, and satisfaction with one's treatment decision. The only difference that emerged by study group was that patients in the CARE group indicated the treatment decision to be somewhat more difficult compared to patients in the GHI group. This is not surprising, given the nature of the CARE intervention, which by reviewing all treatment related issues and connecting those issues to personal goals and values, might have momentarily made the decision somewhat more difficult. We interpret this result as an indication that patients processed the relevant information and that increased perceived difficulty is the "cost" of such processing. When examining this variable at the 6-month assessment point, this difference disappears, further reinforcing that this was a temporal effect. We next examined the long-term effects of the CARE/GHI sessions on the treatment decision variables using data collected at the 6-mo assessment point. There were no differences with regard to worry about treatment decision and distress about the decision. When asked, however, if they would make the same treatment decision again, patients in the CARE condition were significantly more likely to indicate that they would choose the same treatment again compared to patients randomized to the GHI condition. In addition, patients in the GHI condition indicated significantly greater levels of regret about their treatment decision compared to men in the CARE condition. These are preliminary results and should be evaluated with caution, however, they point to the efficacy of the intervention.

OTHER ACCOMPLISHMENTS –YEAR 3:

Since accrual has ended for the study we have focused our efforts on maintaining the return rate for the follow-up assessments. Phone calls and postcards are continually used to remind participants to return the questionnaires. We also have developed a newsletter to keep participants informed about the study and to serve as a reminder to return the questionnaires.

KEY RESEARCH ACCOMPLISHMENTS:

- Continuation of baseline 6-month and 12-month assessments
- Successful return rates for patient and spouse 6-month and 12-month assessments
- Preliminary data analysis
- Submission of preliminary results to national conferences

REPORTABLE OUTCOMES:

Based on our preliminary data analyses of the baseline data set we have submitted two conference abstracts for the annual meetings in 2004 of the American Society of Preventive Oncology (ASPO) and the Society of Behavioral Medicine (SBM).

TREATMENT DECISIONS AMONG PROSTATE CANCER PATIENTS AND SPOUSES: RESULTS FROM A RANDOMIZED TRIAL

Michael A. Diefenbach, Ph.D., Jenevie Dorsey, Ms H.ED; Eric Horwitz, M.D., Robert Uzzo, M.D., Richard Greenberg, MD, Alan Pollack, MD, Susan Raysor, MS., Doris Gillespie, Fox Chase Cancer Center, Philadelphia

A PATIENT-SPOUSE CENTERED INTERVENTION TO FACILITY TREATMENT DECISION MAKING FOR LOCALIZED PROSTATE CANCER: RESULTS FROM A RANDOMIZED TRIAL.

Michael A. Diefenbach, Ph.D., Jenevie Dorsey, MsHED; Eric Horwitz, M.D., Robert Uzzo, M.D., Richard Greenberg, MD, Alan Pollack, MD, Susan Raysor, MS. Doris Gillespie, Fox Chase Cancer Center, Philadelphia

CONCLUSIONS:

We have used the third year to complete baseline data collection and continue to obtain follow-up assessments. By the end of the active recruitment phase we conducted 300 CARE or GHI sessions. Questionnaires are processed, entered in the database, verified, and cleaned. We have continued to conduct preliminary data analysis and have found some promising results that underscore the efficacy of our intervention. These results have been submitted for presentation to two national conferences. Our efforts for the final year in no-cost extension will focus on achieving a maximum return rate of the outstanding follow-up questionnaires, continued data analysis and write-up of manuscripts.

REFERENCES: None

APPENDICES: None